

REMARKS

Claims 1-43 are all the claims pending in the application of which, 1-18 are withdrawn from consideration.

Claims 19-43 are rejected.

New claim 44 is filed herewithin.

Claims 19-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of US 6837892 in view of Mittelstadt et al. (US 6322567, hereinafter “Mittelstadt”).

Claims 19-30, 37 and 40-43 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31-33, 37, 38 and 42 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 19, 20, 24, 25, 27, 31, 33, 34, 36 and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mittelstadt in view of Matsen, III et al. (US 5690635, hereinafter “Matsen”).

Claims 21, 28, 30, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mittelstadt in view of Matsen as applied to claims 19, 20 and 31 above, and further in view of Kienzle, III (US 6718194).

Claims 22, 23 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mittelstadt in view of Matsen as applied to claims 19 and 31 above, and further in view of Glassman et al. (US 5408409, hereinafter “Glassman”).

Claims 26 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mittelstadt in view of Matsen as applied to claims 25 and 34 above, and further in view of Lang et al. (US 6690761 hereinafter “Lang”).

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mittelstadt in view of Matsen as applied to claim 19 above, and further in view of Navab et al. (US 2002/0094189, hereinafter “Navab”).

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mittelstadt in view of Matsen and Kienzle as applied to claim 37 above, and further in view of Navab.

The Applicants traverse the rejections and request reconsideration.

The applicants have carefully studied the outstanding Office Action. The proposed claims have been amended to more distinctly and clearly recite the features of the present invention claimed over the prior art cited. The present amendment is intended to be fully responsive to all points of rejection raised by the Examiner, and is believed to place the application in condition for allowance. Favorable reconsideration, and allowance of the application are respectfully requested.

I. Double Patenting

Rejection of Claims 19-43 are on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of US 6837892 in view of Mittelstadt.

The applicants respectfully request clarification of this rejection. The Applicants respectfully submit that, the only claims currently pending in the present application in which there is recited a robot mounted on a bone of a subject, are claims 42 and 44. The

applicants submit hereinbelow that independent claim 44 cannot be rendered obvious by combination of Mittelstadt et al. with any other prior art.

Furthermore the examiner's statement about "providing robotically guided orthopedic surgery using real-time feedback of imaging methods" does not relate specifically to the subject matter of any of the present claims, but is simply a general statement of aims. The Examiner is requested to provide additional support for his position. The Applicants also request the Examiner to hold the status of this rejection in abeyance pending resolution of all other issues related to patentability of the claims.

II. Claim Rejections Under 35 U.S.C. § 112

Rejection of Claims 19-30, 37 and 40-43, based on section 112, second paragraph

Claims 19-30 and 40-43 stand rejected since they "are directed to an imaging system, though no structure has been set forth to provide means for imaging in the claims." Claim 40 has been canceled, rendering the rejection in its case as moot. The applicants have amended claims 19-30 and 41-43 by deleting recitation of the description "imaging" of the system. The applicants consequently respectfully request withdrawal of this rejection of claims 19-30 and 41-43.

Claim 22 stands rejected since it recites the limitation "said imaging system" in lines 1 and 2. The Examiner contends that there is insufficient antecedent basis for this limitation in the claim. The applicants have amended claim 22 by deleting recitation of the description "imaging" of the system. The applicants consequently respectfully request withdrawal of this rejection of claim 22.

Claim 29 stands rejected since it recites the limitation "said edge detection routine" in lines 1 and 2. The Examiner contends that there is insufficient antecedent basis for this limitation in the claim. The applicants respectfully submit that in element (i) of claim 28, there is antecedent basis for this limitation. Therefore, the Applicants respectfully request withdrawal of this rejection.

Claim 37 stands rejected as being indefinite in that it is unclear as to what claim it depends from. The applicants have deleted the superfluous "2" appearing in the claim and request withdrawal of this rejection of claim 37.

Claims 40-42 stand rejected as being indefinite in that the claims attempt to further define an unclaimed element. The applicants have converted depleted claim 40, rendering this rejection moot. New claim 44 is presented for examination. New claim 44 incorporates all of the subject matter of the underlying base claim 19. Claims 41 and 42 have been amended to depend from new claim 44. The applicants therefore respectfully request withdrawal of this rejection of claims 41-42.

III. Claim Rejections Under 35 U.S.C. § 101

Claims 31-33, 37 and 38 stand rejected under 35 USC 101 because these are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to a particular machine.

The Applicants respectfully submit that since the mailing of this Office Action, the US Supreme Court has issued its decision in *In Re Bilski*, clarifying that the "machine or transformation" test is not the only test to determine patentable subject matter. In addition,

even under the “machine or transformation” test, the present claims are believed to pass muster.

Moreover, the applicants have amended claim 31 to include the steps of:

"using said imaging system to obtain at least one image of said target guide hole"

and

"using said imaging system to obtain at least one image of said target hole"

The applicants respectfully submit that the above amendments make it further clear that the method of claim 31 is tied to a particular machine, and is therefore directed to statutory subject matter. Withdrawal of this rejection is therefore earnestly requested.

Claim 42 stands rejected under 101 because it claims the body part as part of the claimed invention by positively reciting the robot as being mounted on the bone. The Applicants respectfully submit that the bone itself is not being claimed but rather the robot and its location. However in order to avoid any potential misunderstanding of the subject matter of this claim, applicants have amended claim 42 to recite that the robot is adapted to be mounted on the bone. Withdrawal of this rejection is therefore earnestly requested.

IV. Claim Rejections Under 35 U.S.C. § 103

The examiner has rejected claims 19, 20, 24, 25, 27, 31, 33, 34, 36 and 40-43 under 35 U.S.C. 103(a) as being unpatentable over Mittelstadt et al. (US Pat. No. 6,322,567) in view of Matsen, III et al. (US Pat. No. 5,690,635)

The examiner asserts that "Mittelstadt et al. ('567) teaches a system for determining the initial spatial relationship between the surgical robotic arm and the bone can be

accomplished in a variety of ways using radio-opaque marker pins." The examiner then proceeds to explain the way in which Mittelstadt et al. use such marker pins to register the surgical robotic arm to the bone (see column 2, lines 37-53).

The examiner then adds that "(a)s an alternative to using marker pins 51, 52, and 53 on bone 50, to register surgical robotic arm 20 to bone 50, it is also possible to use an optical, mechanical or ultrasound imaging system in conjunction with a pre-surgical image of bone 50 to determine the position and orientation of surgical robotic arm 20 with respect to bone 50 by the recognition of anatomical features thereon as described above."

The examiner then states that "(a)lthough Mittelstadt et al. (567) does not explicitly teach the use of alignment with drill holes, Matsen, III et al. ('635) from the same field of endeavor do teach determining the position and orientation of a drill guide relative to the desired position of a prosthesis (see column 8, lines 38-40; and figure 27).

Consequently, the examiner concludes that "It would be obvious to one of ordinary skill in the art to combine the two registration methods of Mittelstadt et al. with the drilling guide and alignment methods of Matsen, III et al. for the purpose of providing robotically guided orthopedic surgery using real time feedback of imaging methods."

However the applicants having difficulty in determining to what part of the subject matter of the present claims this statement relates, and the applicants would appreciate more specific details of the examiner's grounds for rejection. Nowhere in the present claims is there recited or suggested either of the registration methods of Mittelstadt. Thus, no pre-surgical image of the bone with the marker pins attached, as stated by the examiner, is necessary in the present invention nor is such recited in any of the claims. Furthermore, the

applicants do not understand how the alternative method of registration described in Mittelstadt et al., using an optical or ultrasound system, could be operable for the present claimed invention, since it is unlikely that such systems could locate the position of parts of the target, such as the target hole, within a bone (although that is not specifically recited in the claims).

Nowhere in the present claims is there anywhere recited any registration of the robot to the bone on which it is mounted. The present claimed invention only needs knowledge of the relative pose of the implant hole and the robot arm, and not of the anatomical landmarks or the fiducials. Indeed the whole advantage of the presently claimed invention is that the positions of the target guide hole and of the target hole are determined from independent images generated by the system, and the registration claimed is that of relating the positions of the two holes to each other, such that the robot can align the target guide hole with the target hole. The present claimed invention therefore overcomes some disadvantages of prior art systems such as that of Mittelstadt et al., which require registration and tracking of the robot relative to the bone, as suggested in the background section of the present application, on page 4, lines 8-12, where it states that:

"In such systems," (referring to robot-based Computer Integrated Surgery systems) "bone immobilization or real-time dynamic tracking are important issues, since the relative configuration of the bone with respect to the robot must be known precisely at all times. This may complicate the registration procedure and may adversely affect the overall system accuracy."

The present claimed invention overcomes such potential problems by not requiring bone immobilization or real-time dynamic tracking, and no such procedures are claimed. The target guide hole can be aligned in its image either by the use of radiographically opaque fiducials (which, as recited, *inter alia*, in claim 24, and unlike Mittelstadt et al, are located on the target, and not on the bone), or by observation of the extent of the ellipticity of the imaged hole (as recited, *inter alia*, in claim 21). Nowhere are the methods of Mittelstadt et al. of registration of the robot to the bone by means of physical contact with the marker pins or by imaging of anatomical features of the bone, claimed or suggested in the present application.

The applicants therefore submit a skilled artisan would not have found it obvious to practice the present invention from the combined teachings of Mittelstadt et al. with any other prior art.

In light of the above arguments, the Applicants therefore respectfully submit that none of claims 19, 20, 24, 25, 27, 31, 33, 34, 36, 41-43 and new claim 44 can be considered obvious in the light of Mittelstadt et al. in view of Matsen, III et al., and are all deemed allowable. The applicants therefore respectfully request withdrawal of the examiner's applicable rejection of these claims under 35 USC 103(a).

Furthermore, all of the other claims currently pending in the application, as amended where relevant, are variously dependent on independent claims 19, 31 or 44, and recite additional patentable subject matter. These claims are therefore also deemed allowable.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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